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ORIGINAL ARTICLE

Clinical and Procedural Characteristics of Successful Transcatheter Device Closure of Ostium Secundum Atrial Septal Defect in Symptomatic Children Weighing <15 kg: A Retrospective Study Spanning One Decade From South India

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Abstract

Objectives: **This retrospective study sought to determine the feasibility of transcatheter atrial septal defect device closure in patients less than 15 kg, as well as to assess complication rates and the reasons for unsuccessful device closure.**

Background: **In general, the risks associated with transcatheter atrial septal defect device closure are believed and reported to be relatively low, but the evidence stems from trials involving adults and older children. Current guidelines do not recommend atrial defect closure in device closure in children <15 kg, due to limited data available for feasibility and safety of device closure in this group of patients.**

Methods: **Retrospective review of all patients who underwent elective transcatheter closure of ostium secundum atrial septal defect between September 2013 to February 2022. We excluded all children above 15 kg, as well as those with complex congenital heart defects. Major and minor complications were predefined and indications for referral were evaluated.**

Results: **We identified 81 patients meeting criteria with a median procedural age of 3 years (1 year−8 years), and median weight of 12 kg (4−15 kg). Successful device closure was achieved in 95.1% (77/81) and in 4.9% (4/81), the procedure was aborted. There was 1 major (1.2%) and 1 minor (1.2%) complication, total complication rate (2.4%). 100% of the referrals had right heart enlargement and exertional dyspnoea, 18.5% had recurrent lower respiratory tract infection and 9.9% had failure to thrive. Rate of resolution of residual shunt was 95.1%.at post-procedure day 1 and 98.8% at post-procedure 3 and 6 months respectively.**

Conclusions: **Percutaneous atrial septal defect closure can be done effectively and safely in symptomatic children weighing less than 15 kg in experienced centres. However, deferral for closure until the historically established timeline of around 4−5 years of age should be strongly considered in asymptomatic children.**

Keywords: Atrial septal defect, Small children, Transcatheter device closure

1. Introduction

The successful non-surgical closure of atrial septal defects (ASD) was first described in 1974 by King and Mills [1]. Since, then multiple studies have described the safety and efficacy of the percutaneous approach and suggested it to be the preferred method of closure over surgery in certain patients [2−4]. The complication rates are very low and success rate is very high in selected patients. These studies, however, were based on older and larger patients than are often referred today. There

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is very little published data on transcatheter ASD closure in younger and smaller patients, and the available data is inconsistent with the complications mentioned in previous studies [5–9]. Current guidelines do not recommend transcatheter closure of atrial septal defect in children weighing less than 15 kg due to high likelihood of complications [10], also the most comprehensive data describing adverse event rates in congenital cardiac catheterization did not stratify results according to patient size [7]. Our goal was to assess clinical and procedural characteristics of successful device closure in symptomatic children weighing less than 15 kg, determine our institutional complication rates for elective percutaneous ASD closure in patients less than 15 kg, and to evaluate the various reasons for unsuccessful device closure and referral for surgical closure in a single tertiary care centre in South India. To our knowledge this is the largest cohort ever published in India for transcatheter closure of atrial septal defect in symptomatic children weighing less than 15 kg.

Abbreviation

ASD	Atrial Septal defect
AV	Atrioventricular
ECG	Electrocardiogram
IAS	Inter Atrial Septum
IVC	Inferior Vena Cava
LA	Left atrium
LSVC	Left Superior Vena Cava
OS ASD	Ostium Secundum Atrial Septal Defect
PA	Pulmonary Artery
PAH	Pulmonary Artery Hypertension
RA	Right Atrium
RBBB	Right Bundle Branch Block
RCFA	Right Common Femoral Artery
RUPV	Right Upper Pulmonary Vein
RV	Right Ventricle
SVC	Superior Vena Cava
TAPSE	Tricuspid Annular Plane Systolic Excursion
TEE	Trans Esophageal Echo
TTE	Trans Thoracic Echo
TR	Tricuspid Regurgitation
VSD	Ventricular septal defect

2. Methods

2.1. Study design

This was a single-centre retrospective study conducted in the department of cardiology, Christian medical college, Vellore, India. Our electronic patient database which includes records of cardiac catheterisation, was searched for all patients having undergone a successful or attempted but aborted percutaneous ostium secundum ASD (OS ASD) closure during a 9-year period (September 2013 to February 2022). The study analysed all patients with ostium secundum ASD who weighed less than 15 kg.

In all cases, the procedure was carried out under general anaesthesia and assisted by fluoroscopy and transthoracic echocardiography (TTE). Transoesophageal echocardiography (TEE) was done only if required. Standard catheterization of the right heart was performed with measurement of pulmonary artery (PA) pressure prior to deployment of device. The records were reviewed, including pre-procedure and all follow-up clinical notes, admission and discharge documentation, catheterization reports, electrocardiograms and Holter reports. Echocardiogram reports were reviewed from the time of referral, post-catheterization day 1 and before discharge. Additional echocardiogram reports were reviewed as needed if complications occurred.

3. Study outcomes

The primary outcome was to assess procedural success, defined by deployment of device in stable position with no residual shunt as assessed by fluoroscopy and transthoracic echocardiography.

Secondary outcomes were:

1) To assess the rate and types of complications.
2) Residual shunt rate.

The complications were predefined and stratified into major and minor categories as listed below. Short-term complications were predefined to include anything discovered during the procedure as well as the first 30 days post procedure.

Major Complications:

1. Death.
2. Cardiac or respiratory arrest.
3. Stroke.
4. Device erosion.
5. Device embolization.
6. Need for emergent surgical procedure.
7. Need for re-catheterization for device removal.
8. Significant pericardial/pleural effusion requiring intervention.
9. Persistent dysrhythmia or lethal intraprocedural arrythmia requiring cardioversion/resuscitation.
10. Any new valvular insufficiency or pulmonary vein obstruction.
11. Access site complications requiring intervention or prolong hospital stay.

12. Need for transfusion due to significant bleeding.
13. Permanent limb injury.

Minor Complications:

1. Transient arrythmia resolving with only catheter manipulation.
2. Rebleeding from access site (not necessitating transfusion).
3. Significant access site hematoma.
4. Prolong transient access site paraesthesia.
5. Trivial pericardial/pleural effusions.
6. Deployment malfunctions.
7. Development of post-procedural lower respiratory tract infection.

4. Statistical analysis

For all patient and procedural data, mean ± SD and median (IQR) were calculated for continuous data and frequencies with percentages for categorical variables. Multivariable adjusted odds ratio (OR) with accompanying 95% confidence intervals were reported. A p value less than 0.05 was set for statistical significance. Statistical analyses were performed using Statistical Package for Social Sciences (SPSS), version 21 (IBM, Armonk, NY, USA).

5. Results

The general characteristics of the patients underwent percutaneous OS ASD device closure are mentioned in Table 1. Total of 81 patients of weighing less than 15 kg underwent device closure and the median age was 3 years. 53.1% (43/81) children were females and 46.9% (38/81) were males in this study group. All the patients were symptomatic and had dyspnoea on exertion at least of class II as per modified Ross heart failure classification. Failure to thrive as defined by weight for height below the 5th percentile on standard growth chart or Z - score less than −2 [11], this was seen in 9.9% (8/81) of patients. Frequent respiratory tract infections, defined as ≥6 events per year (or part thereof) requiring antibiotics [12], were present in 18.5% (15/81) of the patients. Most associated cardiac conditions with OS ASD were pulmonary stenosis (8.6%), persistent left superior vena cava (5%) followed by mitral valve prolapse (2.5%) and peri membranous ventricular septal defect (2.5%).

Table 1. General characterstics (n = 81).

	median (IQR) or % (n/N)
Age (years)	3 (1–8)
Male	47% (38/81)
Female	53% (43/81)
Weight (kg)	12 (4–15)
Failure to thrive	9.9% (8/81)
Recurrent lower respiratory tract infection	18.5% (15/81)
Associated cardiac conditions	8.6% (7/81)
- Pulmonary stenosis	5% (4/81)
- Persistent LSVC	2.5% (2/81)
- Mitral valve prolapse	2.5% (2/81)
- VSD (Perimembranous)	2.5% (2/81)

6. Electrocardiographic characterstics

The ECG abnormalities associated with OS ASD in our study population included right axis deviation being the most common ECG abnormality (66.6%), incomplete RBBB (54.3%), right ventricular hypertrophy (13.6%), complete RBBB (9.8%). Though conduction abnormalities are rare in OS ASD and mostly seen in familial ASD's with mutations in NKX2.5, GATA4, TBX5j. In our study 3.7 (3/81) patients had first degree AV block and 2.5% (2/81) had junctional rhythm. None of the patients had high grade AV blocks or ventricular arrythmias.

7. Device and defect charachteristics (Table 2 and Figs. 1–3)

Transthoracic echocardiography was done for all the patients pre procedure, day 1 post procedure and pre discharge. Since TEE requires general anaesthesia in children it was only done in 3 patients for ASD assessment, hence only TTE measurements were used for statistical analysis. For patients who had complications or residual shunts transthoracic echocardiography was performed at 3rd and 6th month. The median diameter of ASD in our patient population was 16 mm (7–26 mm).

In 50% of patients additional Balloon sizing [13] during procedure was done by stop flow technique using Equaliser balloon (Boston Scientific, Natick, MA, USA) following which the device size was determined.

Deficient rims were defined by septal tissue length of any of the aortic rim, atrioventricular valve rim, superior vena cava (SVC) rim, inferior vena cava (IVC) rim, posterior rim or right upper pulmonary vein (RUPV) rim bordering the ASD was less than 5 mm in length [14]. Absent rim meant that no septal tissue was present, and the ASD was direct border forming with the aorta, atrioventricular valve, superior vena cava (SVC), inferior vena cava (IVC) posterior or right upper pulmonary vein (RUPV) region of the septum. Deficient rims were present in 43.2% (35/81) of patients. The most common deficient rim was aortic rim 62.8% followed

Table 2. Defect and device characteristics.

	n = 81
ASD diameter by TTE (mm) (Median (IQR))	16 (7–26)
Deficient rim % (n/N)	43.2% (35/81)
- Aortic rim	62.8% (22/35)
- Posterior	17.1% (6/35)
- IVC (Inferior Vena Cava)	11.4% (4/35)
- Others/Multiple	8.5% (3/35)
Absent rims % (n/N)	4.9% (4/81)
- Aortic rim	50% (2/4)
- Posterior	50% (2/4)
- IVC (Inferior Vena Cava)	50% (1/2)
Right atrial (RA) and Right Ventricular (RV) dilatation % (n/N)	100% (81/81)
Tricuspid Regurgitation (TR) % (n/N)	
- Mild	77.7% (63/81)
- Moderate and severe	22.3% (18/21)
RV dysfunction by TAPSE % (n/N)	2.5% (2/81)
Pulmonary artery hypertension % (n/N)	
- Mild	42% (34/81)
- Moderate	5% (4/81)
- Severe	Nil
Additional Balloon sizing of defect % (n/N)	49% (40/81)
Defect size by balloon mm (Median (IQR) (n = 41/81)	18 (14–26)
Device oversize based on Echo sizing of defect (Average (min–max) %)	10% (0–40%)
Device oversize based on Balloon sizing of defect (Average (min–max) %)	4 % (0–12%)
Device Size mm (Median (IQR)	16 (10–28)
Defect to Weight ratio	
(Mean ± SD)	1.31 ± 0.42
(Median (IQR)	1.33 (1.07–1.66)
Device to Weight ratio	
(Mean ± SD)	1.45 ± 0.44
(Median (IQR)	1.5 (1.16–1.8)
Device to Defect ratio	
(Mean ± SD)	1.11 ± 0.14
(Median (IQR)	1.12 (1.05–1.20)
Sheath size used (Fr) (Median (IQR)	
Venous	9 (7–9)
Arterial	4 (4–5)

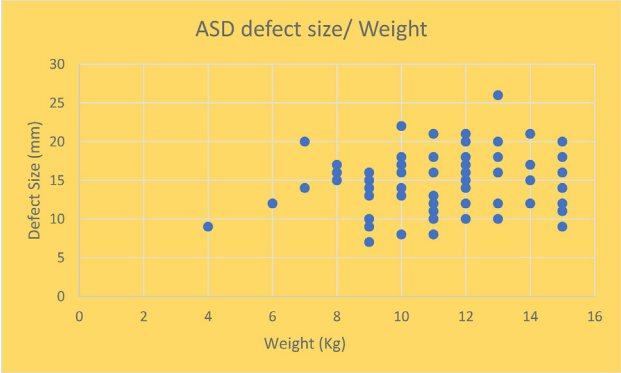

Fig. 1.

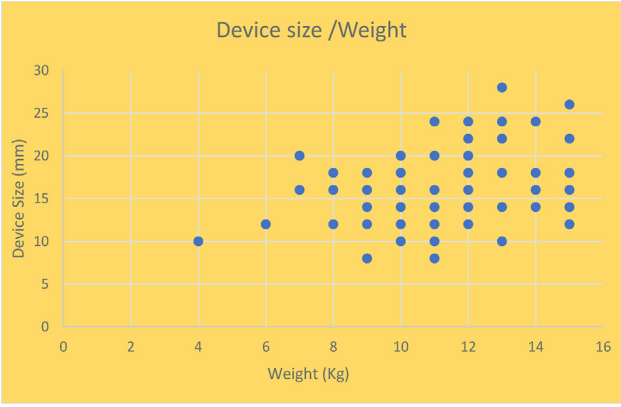

Fig. 2.

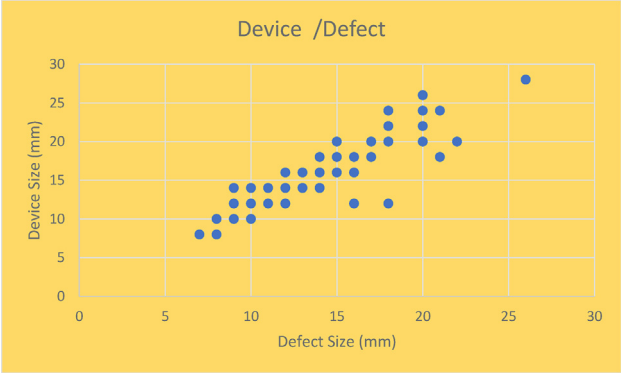

Fig. 3.

by posterior rim 17.1% and IVC rim 11.4%. Absent rims were seen in 4.9% (4/81), the most common rim to be absent was aortic rim followed by posterior respectively. Right heart dilatation was seen in 100 % (81/81) of patients. Mild tricuspid regurgitation was present in 77.7% (63/81) of the patients and moderate to severe tricuspid regurgitation in 22.3% (18/81) of patients. Only 2 out of 81 patients (2.5%) had right ventricular dysfunction at diagnosis.

PA pressure was measured by pulmonary artery catheterization prior to ASD closure. Normal PA pressure was defined as mean PA pressure less than 20 mmHg [15].

Pulmonary hypertension (PAH) was graded as follows:

1. Mild: Systolic PA pressure was <1/3 of systolic systemic pressure,

Table 3. Device implanted (n = 81).

Device	N (%)
LifeTech cera ASD occluder	57 (70.4%)
Amplatzer septal occluder	20 (24.7%)
MemoPart ASD occluder	4 (4.9%)

2. Moderate: Systolic PA pressure between 1/3 2/3 of systolic systemic pressure
3. Severe: Systolic PA pressure >2/3 of systolic systemic pressure.

Mild PAH was observed in 42% (34/81) of the patients and moderate PAH in 5% (4/81) of the patient. Majority of patients did not have pulmonary artery hypertension and none of them had severe PAH to warrant a reversibility study.

8. Sheath size

The median size of venous sheath used was 9 Fr (7–9. Fr) and arterial sheath used was 4 Fr (4–5 Fr).

9. Device implanted

The device implanted were- Amplatzer, Lifetech and Memopart (Table 3). The median size of device implanted was 16 mm (10–28 mm).

10. Technical modifications

In our study population the mean ASD diameter (mm) to weight (kg) ratio was 1.16:1. 11 patients had ratio of ≥2:1. 6 out of 11 (54.5%) patients with the defect to weight ratio ≥2:1 and required modification in deployment technique as described:

1. Right upper pulmonary vein (RUPV) deployment: Deployment of the left atrial disc at RUPV and left atrium junction and then pulling the opened disc on to inter atrial septum helps to maintain the device parallel to the interatrial septum and prevent the rotation and prolapse of the device through the large ASD with deficient rims [16].
2. Left upper pulmonary vein (LUPV) deployment: The left atrial disc is deployed within LUPV and remains constrained until the right atrial disc is unsheathed quickly causing the right atrial disc to engage first to the septum before the induced tension pulls the left atrial disc towards the septum for engagement [17].
3. Balloon assisted deployment [18], is another technique where an inflated balloon across the septum through alternate venous access is used to support the device during deployment across the large defect with deficient rims.

5 out 6 (83.3%) underwent pulmonary vein deployment (4 in left upper pulmonary vein and 1 in right upper pulmonary vein) and 1 required balloon assisted device closure.

11. Outcomes of device implantation

Out of 81 patients who underwent ASD device closure, 95.1% (77/81) were successful and 4.9% (4/81) were unsuccessful. The patient characteristics and reasons for unsuccessful procedure and referral for surgery are mentioned below.

Patient 1: 3-year-old girl presented with recurrent lower respiratory tract infection with failure to thrive, TTE revealed 22 mm OS ASD, despite of multiple attempts the device (22 mm–24mm) did not show good apposition and not holding the rims. As the ASD diameter (mm) to weight ratio (kg) 2.1:1 (large ASD size for body weight) hence the procedure was deferred, and the patient was referred for surgical ASD closure.

Patient 2: 3-year-old girl otherwise asymptomatic with RA RV dilatation and 10 mm OS ASD with aneurysmal IAS, before deployment of 14 mm device she went into complete heart block with reverted to sinus rhythm in repositioning the device back into the sheath. Hence the procedure was deferred, and the patient was referred for surgical ASD closure.

Patient 3: 1- year-old boy presented with recurrent lower respiratory tract infection requiring hospitalization, TEE revealed fenestrated ASD with total size measuring 15 mm and aneurysmal IAS and deficient Inferior vena cava (IVC) and posterior rims. 16 mm device was attempted multiple times, but the rims could not be caught. As the ASD diameter (mm) to weight ratio (kg) 2.3:1 (large ASD size for body weight) hence the procedure was deferred, and the patient was referred for surgical ASD closure.

Patient 4: 5-year-old boy presented with recurrent lower respiratory tract infection with RA RV dilatation and 16 mm OS ASD and aneurysmal IAS with deficient posterior and IVC rims, 18 mm device was attempted multiple times, but the rims could not be caught. Hence the procedure was deferred, and patient was referred for surgical ASD closure.

12. Complications (Table 4)

Out of 81 procedures done only 2 patients had complications, first patient had access site complication – right common femoral artery thrombosis – major complication and second patient had transient complete heart block – minor complication. All the other patients had uneventful procedure and were discharged post op day 1 or 2.

Table 4. Patient characterstics with complications.

	Age	ASD size	Device size	Complication	Outcome
Patient 1	5 years	18 mm	22 mm	Right common femoral artery thrombosis (Major)	Therapeutic anticoagulation – Spontaneous recanalization of RCFA after 3 months
Patient 2	3 years	14 mm	14 mm	Complete heart block – Transient (Minor)	Procedure abandoned – Referred for surgical ASD closure

13. Residual shunts (Table 5)

The residual shunts post device implantation was seen in 4.9% (4/81) patients on post op day 1, all the patients were asymptomatic. The 3 months post op TTE showed spontaneous closure of residual shunts in 3 out of 4 patients, but the 1 patient had persistent residual shunt even at 6 months follow up.

14. Discussion

Historically, the recommendation for elective ASD closure from surgical literature was to wait until around 4 years of age [19]. The previous studies have shown a high rate of spontaneous closure of ASD less than 8 mm in the first few years of life [19–23], and sometimes in late adolescence [24]. Due to the known high rates of spontaneous closure in ASD less than 10 mm in the first year of life, proceeding rapidly to close an ASD in an asymptomatic young patient is not advisable in previous studies [25]. However, in symptomatic children there is scarcity of data for transcatheter closure of ASD [5–9], and current guidelines also do not recommend transcatheter closure of atrial septal defect in children weighing less than 15 kg due to high likelihood of complications [10]. This study was done to determine the feasibility of transcatheter ASD closure in symptomatic children less than 15 kg and assess the rates and types of complications associated with it.

The median ASD diameter was 16 mm in our study which suggests that most of these defects may not have closed spontaneously had we not intervened. It has been shown that some ASDs can enlarge over time, even to the extent of outgrowing percutaneous closure capability [26]; however, this typically occurs in older children and was not a factor in our study. As the experience in structural heart disease interventions is increasing the percutaneous device closure of ASD has progressed, along with numerous studies concluding it to be safe and the preferred method over surgery, referrals for younger patients have become more frequent. There is ample evidence to suggest percutaneous closure is preferred in older children with respect to decreased morbidity [2]. Most common Indication for closure of ASD in small children is ventricular volume overload and right heart enlargement, present in all patients (81/81) in our study, besides these the other indications that have historically been considered acceptable for elimination of any intracardiac shunt were the documentation of recurrent lower respiratory tract infections and failure to thrive [27–29], which was seen in 18.5% (15/81) and 9.4% (8/81) children respectively in our study.

Table 5. Residual shunts.

	Post procedure day 1	Post procedure at 3 months	Post procedure at 6 months
Residual shunt	4.9% (4/81)	1.2% (1/81)	1.2% (1/81)

Successful device implantation was established in 95.1% (77/81) of our patients and in 4.9% (4/81) of the patients the device implantation was unsuccessful. The success of device closure greatly depends on choosing the correct size of the device. In our study the size of the defect was routinely assessed by standard transthoracic or/, but about 50% of patients underwent additional balloon sizing during the procedure [12]. In our study the device was on an average oversized by 4.06% (min 0-max 12%) compared to balloon size. In the patients where balloon sizing was not done the device size was oversized on an average by 10% (min 0- max 40%) from the size of the maximum measured defect determined by TTE, thus indicating that balloon sizing led to use of comparatively smaller sized devices which were best fit across the defect.

Earlier studies have advised against closing the ASD in children when the size of the defect is 1.5–2 times the weight of defect in kgs [5,30]. However, with advance in transcatheter interventions defects more than the 300% the size of the body weight have been closed effectively and safely [8]. In our study the mean defect to weight ratio was 1.31 ± 0.42, with the largest defect being 2.85 times the weight of child, which was closed successfully and safely. Around 40% patients in our study had defect to weight ratio of more the 1.5 and 12% had ratio more than 2, thus clearly demonstrating that in current era that defect to weight ratio is no limitation for transcatheter atrial septal defect closure.

In small children the left atrial (LA) size is small resulting in its inability to accommodate the opened left atrial disc, especially when the device required is large, thus resulting in the malalignment of the LA disc with the plane of the IAS causing prolapse of the device across the defect. The routine method of deployment can fail under such circumstances and slight modifications in the technique of deployment is helpful in achieving appropriate position of device across the defect [31]. In our study the mean device to weight ratio was 1.45 ± 0.44, and most of the device deployment was done conventionally, however 15% patients had device to weight ratio greater than 2:1 out of which 50% required technical modification for successful device closure. Pulmonary vein deployment was done in 5 children (4 in left upper pulmonary vein and 1 in right upper pulmonary vein) and 1 child required balloon assisted device closure.

The residual shunt post device implantation was seen in 4.9% (4/81) patients on post op day 1, all the patients were asymptomatic. The 3 months post op transthoracic echocardiography showed spontaneous closure of residual shunt in 3 out of 4 patients, but the 1 patient had persistent residual shunt even at 6 months follow up.

The complications rate in our study was 2.4%, which is very low and as compared to other similar studies done where complication rates 3–4% [32,33]. In our study only 2 patients developed complications One patient had access site related venous thrombosis which was treated with anticoagulation, while other patient had transient complete heart block during deployment of device which reverted to sinus rhythm once device was retrieved back, and patient was then referred for surgical closure. Reversible conduction blocks during device closure in children have been reported and sometimes are transient and reversion usually occurs within 1–2 days with use of steroids and atropine, without the need for device to be removed [9], However sometimes surgical removal of the device is necessary [34,35].

In our study successful device closure could not be achieved in 4.9% children (4/81). In one patient the defect was large (Defect/Weight ratio 2.1), while in two patients the failure to deliver the device in stable position was due to deficiency of IVC and posterior rim with associated aneurysmal inter atrial septum. Although device embolization is reported more often while closing large defects, it is the deficient margins associated with these large defects or under sizing of the device in terms of its relation to the largest diameter which is usually the reason for it [5,28,30]. In our centre the practice is to send for surgical closure if 2 or more of the inferior, superior or atrioventricular valve rims are deficient or absent. Deficient or absent aortic rim is not considered as a contraindication for transcatheter closure, as seen in our study 68% patients had a deficient Aortic rim, despite that the device closure was successful, however deficient aortic rim is a risk factor for device erosion [36,37], but it was not encountered in any of our patients. Thus, choosing the appropriate size of the device is the Achilles heel of successful transcatheter ostium secundum ASD closure.

14.1. Study limitations

This is a retrospective study. Even though this study is the largest yet reported in India, population size remains small, and more research is needed in this area. Our cohort is heterogeneous, making it difficult to have a control group.

15. Conclusion

Percutaneous ASD closure in children less than 15 kg symptomatic children is effective with a 95.1% procedural success rate, a 1.2 % rate of residual shunt at 6 months and a very low complication rate. For the truly elective small patient without comorbidities that could be exacerbated by the shunt physiology, including those with poor growth as their sole indication or those with only right heart enlargement on echocardiogram, deferral of closure until the historically established timeline of around 4–5 years of age should be strongly considered. However, our data show that the device closure is not only feasible in symptomatic small children but can be done effectively and safely with great degree of predictability.

Author contribution

Conception and design of Study: SPJ, MSUR. Literature review: SPJ, MSUR, JK. Acquisition of data: SPJ, MSUR, JK. Analysis and interpretation of data: SPJ, MSUR, JK. Research investigation and analysis: SPJ, MSUR, JK, SIV, GBK, OKG, PVG, JJ, VST. Data collection: SPJ, MSUR. Drafting of manuscript: SPJ, MSUR, JK. Revising and editing the manuscript critically for important intellectual contents: MSUR, JK, SIV, GBK, OKG, PVG, JJ, VST. Data preparation and presentation: SPJ, MSUR, JK. Supervision of the research: JK, SIV, GBK, OKG, PVG, JJ, VST. Research coordination and management: SPJ, MSUR, JK. All authors have helped in manuscript preparation, they read and approved the manuscripts.

Conflicts of interest

Nothing to declare.

Acknowledgment

The authors have no financial or nonfinancial conflict of interest to declare.

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